

United States District Court
District of Massachusetts

CARDIOFOCUS, INC.,)
Plaintiff,)
)
v.) Civil No.
) 08-10285-NMG
CARDIOGENESIS CORPORATION,)
Defendant.)
)

MEMORANDUM & ORDER

GORTON, J.

This is a patent infringement action involving laser catheter systems. Plaintiff CardioFocus, Inc. ("CardioFocus") alleges that defendant Cardiogenesis Corporation ("Cardiogenesis") manufactured, used, imported, sold, and offered for sale lasers that infringed at least one of its two patents-at-issue: U.S. Patent Nos. 5,843,073 ("the '073 patent") and 6,547,780 ("the '780 patent"). Cardiogenesis is the only remaining defendant.¹

I. Background

The '780 and '073 patents describe a system for transmitting laser energy via an optical fiber for the purposes of tissue removal and repair. The invention is based, in part, on the

¹ Claims against Trimedyne, Inc. and Convergent Laser Technologies were settled in the Fall of 2010 through alternative dispute resolution. Claims against the remaining defendants, with the exception of Cardiogenesis, were voluntarily dismissed.

discoveries that 1) the wavelengths of infrared radiation emitted by so-called "rare earth" lasers, or lasers with a wavelength between 1.4 and 2.2 micrometers, are strongly absorbed in biological tissue and 2) silica fibers with a low hydroxyl-ion content have the flexibility and high conductivity that enables the transmission of such wavelengths to remote surgical sites to facilitate removal or repair of biological tissue.

CardioFocus argues that Cardiogenesis' products, the TMR 2000, Solargen 2100 and New Star PMC lasers and laser systems, infringe Claims 2 and 7 of the '073 patent and Claim 2 of the '780 patent. Cardiogenesis denies CardioFocus' allegations and brings counterclaims for declaratory judgment of non-infringement and patent invalidity.

The case has been stayed twice, from October, 2008, to April, 2010, and from March, 2011, to August, 2011, pending patent re-examination proceedings before the United States Patent and Trademark Office ("PTO"). With respect to the '780 patent, the PTO found a substantial new question of patentability based on prior art patents and printed publications that expressly teach and recognize a laser surgical system which uses 1) lasers emitting energy at a wavelength in a range of about 0.2-3.0 micrometers and 2) silica fiber having a low hydroxyl-ion content as a means for reducing absorption of the laser energy during transmission of the laser through the fiber. The PTO ultimately

confirmed the patentability of three claims of the '780 patent and rejected the remaining eleven. In response, CardioFocus chose not to pursue the rejected claims and statutorily disclaimed them. With respect to the '073 patent, the PTO confirmed the patentability of five of the claims and CardioFocus statutorily disclaimed the remaining eight.

The Court held a Markman hearing on October 21, 2011, and, on November 3, 2011, issued a Memorandum and Order construing the disputed claim terms ("Markman Order") which defendant has moved this Court to reconsider. Shortly thereafter, the parties filed cross-motions for summary judgment. Defendant has since moved to strike plaintiff's reply briefs on the grounds that they are untimely. Those motions are pending before the Court.

II. Motions for Summary Judgment

A. Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

A fact is material if it "might affect the outcome of the

suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

B. Application

Plaintiff moves for summary judgment on defendant's counterclaim and affirmative defense of inequitable conduct as well as defendant's equitable defenses of laches, estoppel, acquiescence, ratification, unclean hands and waiver.

In its cross-motion for summary judgment, Defendant submits that 1) its Crystal Flex fiber-optic delivery system ("Crystal Flex system") does not infringe the patents-in-suit, 2) the

relevant claims in those patents are obvious and thus invalid and 3) the doctrine of laches bars plaintiff from recovery. The Court reviews the issues of non-infringement and obviousness, respectively, before turning to defendant's equitable counterclaim and defenses.

1. Non-infringement

An infringement analysis requires 1) the Court to determine, as a matter of law, the meaning and scope of the patent claims asserted to be infringed and 2) the trier of fact to compare the properly construed claims to the device accused of infringing. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Summary judgment of non-infringement is appropriate where no reasonable jury could have found infringement even if all reasonable factual inferences were drawn in favor of the patentee. Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1353 (Fed. Cir. 2001).

Defendant submits that the Crystal Flex system does not infringe upon the patents-in-suit because 1) it absorbs approximately 50% of the laser energy transmitted through it and 2) the optical fibers comprising it are neither purified nor treated to reduce the concentration of hydroxyl ions. Such qualities, the defendant maintains, prevent it from meeting the claim limitations "low hydroxyl ion content" (Claims 2 and 7 of the '073 patent), which has been construed to mean "hydroxyl ion

content low enough to prevent laser energy from being highly absorbed in silica fiber," and "means for reducing the absorption of laser energy at a wavelength of about 1.4-2.2 micrometers" (Claim 2 of the '780 patent), which has been construed to mean fiber that has been purified to reduce the concentration of hydroxyl ions including fused silica optical fiber part no. 822W manufactured by Spectran Corporation.

Plaintiff acknowledges that Crystal Flex has the attributed qualities but takes issue with defendant's conclusion that they prevent it from meeting the claim limitations.

Plaintiff has the better of the argument, as is evident from the plain meaning of the construed patent claims. With respect to absorption, the patent specifies only that the hydroxyl-ion content of the fibers must be "low enough to prevent laser energy from being highly absorbed in silica fiber." It does not require the system, as a whole, to prevent energy loss. The defendant admits that the 50% energy loss to which it refers occurs in the air gap between the two sets of fibers. It appears to have nothing to do with the fibers themselves, which, as defendant's own expert acknowledged, have a low hydroxyl-ion content.

In conclusion, plaintiff has adduced sufficient evidence from which a reasonable jury could find that Crystal Flex is partially comprised of a low OH silica fiber through which less than two percent of the laser energy passing through it is

absorbed and which reduces the absorption of laser energy at a wavelength of 1.4-2.2 micrometers. Defendant's motion for summary judgment with respect to infringement will, therefore, be denied.

2. Obviousness

Duly issued patents are entitled to a presumption of validity. 35 U.S.C. § 282; KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 412 (2007). To overcome this presumption and succeed in its obviousness challenge to a patent's validity, a party must demonstrate by clear and convincing evidence that

the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

35 U.S.C. § 103(a). Whether the claims of a patent are obvious is ultimately a question of law, the determination of which is based on findings of fact made with respect to 1) the scope and content of the prior art, 2) the differences between the prior art and the claims at issue, 3) the level of ordinary skill in the pertinent art and 4) secondary indicia of non-obviousness such as commercial success, the failure of others, and copying.

KSR Int'l, 550 U.S. at 406 (quoting Graham v. John Deere Co., 383 U.S. 1, 17 (1966)). Summary judgment for obviousness is appropriate only when the underlying facts are not in material dispute and the obviousness of the claims is so apparent that no

reasonable jury could find otherwise. Id. at 427. Where, as here, the PTO has considered the prior art in the context of a validity challenge during patent re-examination, the burden of proof to invalidate a patent on obviousness grounds is "particularly heavy." Impax Labs., Inc. v. Aventis Pharm., Inc., 545 F.3d 1312, 1314 (Fed. Cir. 2008).

The defendant contends that the claims at issue combine two elements, a Holmium YAG laser and an elongate, low-OH silica fiber, which were in use years before the earliest date to which the patents-in-suit claim priority. Specifically, the defendant points to the collective teachings of the Wurster, Beck and Nath prior art references. Because it would arguably have taken nothing more than common sense to combine the teachings of prior art to derive the combination claimed by the patents-in-suit, those patents should be invalidated on obviousness grounds.

Over the past three years, the defendant has raised the same or similar arguments to the PTO on eight separate occasions in its enduring quest to have the patents-in-suit declared invalid. Each time, the PTO reviewed the prior art, concluded that it "would not be important to a reasonable examiner in deciding the patentability" of the claims at issue and confirmed the validity of the patents. The defendant seeks a ninth bite at the apple.

At the outset, it is worth noting that it was the defendant which moved to stay the case for three years pending patent re-

examination. According to defendant (at the time), a stay would give the PTO the opportunity to use its considerable expertise to resolve the underlying issues of patent validity. Now that the PTO has ruled adversely to the defendant, it seeks to re-litigate the matter in this forum.

Turning to the merits of the defendant's position, the Wurster, Beck and Nath prior art references address different problems and, when considered in their entirety, appear to teach away from the claims at issue. The Wurster reference involves the delivery of laser energy to a surgical site but does not use fibers, a crucial element of the patents-in-suit. The Beck patent likewise makes no reference to fibers and does not emphasize the surgical application of the laser delivery system. The Nath reference discourages the use of low-OH fibers to transmit Holmium YAG laser energy. To be sure, certain portions of those patents describe similar processes and systems as those disclosed in the patents-in-suit. While it is easy, in hindsight, to piece them together and suggest that the solution to the problem was obvious, the defendant must do more than "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1576 (Fed. Cir. 1991). Rather, to succeed in its obviousness challenge, the defendant must point to "some teaching or suggestion in the references to

support their use in the particular claimed combination." Id. That it has not done.

Because genuine issues of material fact remain with respect to the scope and content of the prior art, the differences between the asserted claims and the prior art, the understanding of a person of ordinary skill and secondary conditions of non-obviousness, defendant's motion for summary judgment on obviousness grounds will be denied.

3. Inequitable Conduct

Inequitable conduct is a defense to patent infringement that, if established, bars enforcement of a patent. Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1286 (Fed. Cir. 2011). To prevail on its counterclaim and defense of inequitable conduct, defendant must prove, by clear and convincing evidence, that plaintiff misrepresented or made a deliberate decision to withhold known material information with the specific intent to deceive the PTO. Id. at 1287, 1290. The Federal Circuit has recently tightened the inequitable conduct standard to ensure that the defense is interposed only in egregious circumstances and to discourage parties from using it as a mere litigation tactic in garden-variety cases. Id. at 1288-91.

Defendant's inequitable conduct counterclaim and affirmative defense rest on the contention that affidavits submitted to the PTO by the plaintiff contained statements the inventor and

prosecution counsel knew to be false. Defendant submits that the 822W fibers disclosed in the patents-in-suit were, contrary to representations made by Dr. Sinofsky, commercially available and not purified or specially treated to reduce hydroxyl-ion content. In addition, defendant accuses plaintiff's counsel of withholding material evidence from the PTO during prosecution and re-examination. Plaintiff acknowledges that some of the statements by Dr. Sinofsky were imprecise but disputes that they were intended to deceive or were relied upon by the PTO. Plaintiff denies entirely that its counsel improperly withheld information from the PTO.

Defendant here makes mountains out of molehills. The statements made by Dr. Sinofsky comported with his stated understanding at the time that the 822W fibers he ordered from Spectran Corporation were specially made for him and treated to reduce their hydroxyl-ion concentration. Dr. Sinofsky asked for an ultralow-OH fiber and, when it arrived a few months later, he assumed that it was a custom order and not otherwise available. His understanding was eminently reasonable, if not actually correct. Nor was his representation, as the defendant dramatically states, "the entire basis upon which the claims were allowed."² As this Court stressed in its Memorandum and Order

² Defendant should be made aware that hyperbolic statements and frequent capitalization, bolding and underlining throughout its briefs have the opposite of their intended effect.

construing the disputed terms:

The patents-in-suit describe a more effective way to transmit laser energy to a surgical site using existing fiber optic technology. They do not purport to invent a new kind of fiber and thus need not describe the process for making it.

The process by which the fiber was made and its commercial availability were simply not material to the PTO's decision.

Furthermore, the decision of plaintiff's counsel not to submit depositions and pleadings relating to inequitable conduct to the PTO is consistent with the Manual Patent Examining Procedure ("MPEP"), which provides that such issues "are not considered in re-examination" and instructs parties to refrain from filing pleadings from other proceedings, including depositions and attorney argument. MPEP §§ 2014, 2282. Indeed, the PTO admonished the defendant for submitting such materials in the re-examination proceeding and expunged them from the record.

While defendant presents some disputed issues of fact with respect to its inequitable conduct counterclaim and defense, its accusations are so hyperbolic and immaterial that their submission to a jury would serve only to confuse and distract from the pertinent issues at hand. Plaintiff's motion for summary judgment with respect to inequitable conduct will, therefore, be allowed.

4. Laches

Of the laundry list of equitable defenses asserted by the defendant, laches is the only one which merits extended

discussion. Laches is an equitable defense pursuant to which a party may be barred from relief if that party's delay in bringing the claim was unreasonable and resulted in injury or prejudice to the opposing party. A.C. Aukerman Co. v. R.L. Chaides Const. Co., 960 F.2d 1020, 1034-35 (Fed. Cir. 1992). In the patent context, a statutory presumption of laches arises if a preponderance of the evidence reveals that the patentee delayed filing suit for more than six years after actual or constructive knowledge of the defendant's alleged infringing activity. 35 U.S.C. § 286; id. at 1034-36. As an equitable defense, the doctrine of laches must not be applied mechanically. Rather,

the establishment of the factors of undue delay and prejudice, whether by actual proof or by the presumption, does not mandate recognition of a laches defense in every case. . . . Those factors merely lay the foundation for the trial court's exercise of discretion.

Id. at 1037.

Parties have filed cross-motions for summary judgment on defendant's laches counterclaim and affirmative defense. At the crux of their dispute is correspondence between the parties between 1999 and 2006. The first letter, dated January 8, 1999, to the defendant from the plaintiff's predecessor in interest, Rare Earth Medical, Inc. ("the January 1999 letter"), begins by advising the defendant of the '073 patent and informing it of the patent's surgical applications. The letter goes on to suggest that the defendant might be interested in a "co-exclusive

licensing opportunity" concerning the '073 patent in light of defendant's development of laser systems employing optical fibers. The tenor of the letter is cordial. It does not accuse the defendant of infringement or hint at future litigation.

Six years later, in 2005, plaintiff followed up with a letter urging defendant to "seriously consider" taking a license under its patents and hinting at, though not expressly threatening, possible litigation if defendant declined to do so ("the November 2005 letter"). Unlike the first letter, the second one specifically identifies the allegedly infringing products and provides a chart explaining the ways in which they purportedly infringe upon the '073 patent. The letter is amicable in tone and makes clear that plaintiff would prefer to resolve the dispute out of court.

The parties corresponded six more times between then and July 2006. When defendant asked for more information in December 2005, plaintiff responded:

If Cardiofocus was taking an aggressive litigation posture regarding CardioGenesis and the Laser Patents, I would understand your request for a more comprehensive statement of infringing products and infringed claims. As it stands, I believe our letter of November 29 is sufficiently clear and specific to convey the subject of our interest and the basis for proposing a license under the Laser Patents.

In January 2006, defendant declined plaintiff's invitation for a license and asserted its position that the '073 patent was rendered invalid by prior art. In July of that year, plaintiff

informed the defendant that it had commenced litigation against Lumenis, Inc., another purported infringer, and it was strongly considering amending the complaint in that case to add Cardiogenesis as a defendant if Cardiogenesis did not begin serious discussions to resolve the matter ("the July 2006 letter"). That was the first time plaintiff directly threatened suit.

Defendant responded with more questions to which plaintiff did not reply. In February 2008, plaintiff filed suit in this Court.

Defendant contends that the laches doctrine bars plaintiff's claim to damages with respect to the '073 patent because plaintiff filed the present action over nine years after indirectly suggesting infringement in the January 1999 letter, more than two years after directly alleging infringement and broaching the possibility of litigation in the November 2005 letter and over one year after first expressly threatening suit in the July 2006 letter. Defendant submits that plaintiff displayed bad faith by representing that it was not taking "an aggressive litigation posture," cutting off communication for two years and then filing this action. According to the defendant, the delay caused economic prejudice to its business, including the potentially wasted investment in the allegedly infringing products, and evidentiary prejudice to its defense, such as faded memories and lost documents.

Plaintiff responds that the defendant grossly mischaracterizes

the January 1999 letter, which pertained to products which are neither the subject of this litigation nor related to the allegedly infringing products. The letter inquired whether defendant was interested in a licensing opportunity and did not specifically mention patent infringement. Plaintiff represents that it learned of the defendant's allegedly infringing products only shortly before sending the infringement letter in November 2005. It argues that it should not be disadvantaged for its subsequent efforts to resolve the matter without resorting to litigation.

The threshold issue is whether the January 1999 letter is enough evidence to establish that plaintiff had actual or constructive knowledge of the defendant's alleged infringing activity in 1999, thereby triggering the statutory presumption of laches. Because the January 1999 letter did not specifically describe the products at issue in this case, threaten suit or even mention infringement, it is not enough evidence on which to base a finding of constructive knowledge of infringement. Nor is it reasonable to infer from the fact that plaintiff was on notice that defendant was in the business of developing laser systems generally that plaintiff must have been on notice of the allegedly infringing products at issue in this case.

Having decided that plaintiff was not on notice of the alleged infringement until November 2005, the next question is whether plaintiff's delay in filing suit was unreasonable. The

period between November 2005 and July 2006 will be excused as a good-faith effort to resolve the matter without resorting to litigation. See Aukerman, 960 F.2d at 1033. While plaintiff points to no such justification for the delay between the termination of license negotiations in July 2006 and the filing of the Complaint in February 2008, delays of under three years do not, absent exceptional circumstances, give rise to a finding of laches. See Meyers v. Asics Corp., 974 F.2d 1304, 1307-08 (Fed. Cir. 1992) (finding delay of three years reasonable where it was caused in part by license negotiations); Meyers v. Brooks Shoe Inc., 912 F.2d 1459, 1461-63 (Fed. Cir. 1990) (suggesting that dismissals on laches grounds for delays of under six years are rare and typically involve allegations of misconduct); Studiengesellschaft Kohle mbH v. Dart Indus., Inc., 549 F. Supp. 716, 759 (D. Del. 1982), aff'd 726 F.2d 724 (Fed. Cir. 1984) (holding that three-year eight-month delay was a "relatively short period of time [and] was not unreasonable or inexcusable").

Furthermore, defendant has failed to convince the Court that it was prejudiced by the delay. Defendant has consistently attacked the validity of the patents-in-suit and challenged infringement allegations. Upon receiving the November 2005 letter, defendant made no effort to design around the '073 patent or otherwise alter its business approach. Defendant complains of lost documents and witnesses but has not shown that possession of

such evidence, if it ever existed, would markedly improve its position. Moreover, any prejudice resulting from the passage of time is partially of the defendant's own doing: after all, it was the defendant that repeatedly moved this Court to stay the case pending patent re-examination.

In light of the foregoing, summary judgment with respect to defendant's laches defense and counterclaim will be entered in favor of the plaintiff.

5. Remaining equitable defenses

Defendant has failed to carry its burden of producing sufficient evidence to support its remaining equitable defenses of acquiescence, equitable estoppel, waiver, unclean hands and ratification. Equitable estoppel, acquiescence and waiver cannot be established because there is no evidence that plaintiff represented, directly or indirectly, that it did not intend to enforce its patent rights. Unclean hands is a species of defendant's inequitable conduct defense, which the Court has already resolved. Ratification is an equitable defense commonly asserted in contract cases and does not apply in the context of patent litigation. Accordingly, plaintiff's motion for summary judgment with respect to those defenses will be allowed.

III. Motion for Reconsideration

A. Standard

Ruling on a motion for reconsideration requires a court to

"balance the need for finality against the duty to render just decisions." Davis v. Lehane, 89 F. Supp. 2d 142, 147 (D. Mass. 2000). Reconsideration is warranted only in a limited number of circumstances:

if the moving party presents newly discovered evidence, if there has been an intervening change in the law, or if the movant can demonstrate that the original decision was based on a manifest error of law or was clearly unjust.

United States v. Allen, 573 F.3d 42, 53 (1st Cir. 2009). Such motions are not vehicles for pressing arguments which could have been asserted earlier or for "re-arguing theories previously advanced and rejected." Palmer v. Champion Mortg., 465 F.3d 24, 30 (1st Cir. 2006). The granting of such a motion is "an extraordinary remedy which should be used sparingly." Id.

B. Application

Defendant urges the Court to reconsider portions of its Markman Order "based on newly discovered evidence and to correct clear errors of both law and fact" with respect to certain of the construed terms.

Defendant disputes the Court's construction of the claim term "a flexible, elongate fiber" and requests clarification regarding the construction of "low hydroxyl ion content." The newly discovered evidence to which defendant refers

is the acknowledgment by CardioFocus that the 822W fiber disclosed in the patent are [sic] made from Suprasil W and thus are not "new".

Plaintiff purportedly hid this fact from the PTO and the Court

until four days after the Court's Markman Order. According to the defendant, this information not only bears upon its defense of, and counterclaim for, inequitable conduct, but also affects the validity of the patents and the construction of the claim terms "low hydroxyl ion content" and "means for reducing absorption of laser energy." Had this information been presented to the PTO, the defendant speculates, the patents would not have been confirmed after re-examination.

Far from "new evidence," this is merely another iteration of the argument already pressed by the defendant during claim construction and on summary judgment. See, e.g., Section III.B.3, supra. The term "low hydroxyl ion content" addresses the hydroxyl-ion content present in a component fiber of the claimed surgical system. The fiber's source, brand, newness and manufacturer is not relevant to claim construction. Defendant's request for clarification is little more than an effort to re-litigate the construction of that term. The same consideration bars review of defendant's contention that the Court's construction of the term "a flexible, elongate fiber" is contradicted by the plain meaning of the claim language. The Court considered and rejected the defendant's proposed construction of those terms and finds no reason to re-visit its decision here.

IV. Motion to Strike

Defendant moves to strike plaintiff's reply briefs on the

grounds that they are untimely and to preclude plaintiff from seeking leave to file further replies. Because the Court did not consider the arguments presented in those briefs in ruling on the foregoing motions for summary judgment, the motion to strike will be denied as moot.

ORDER

In light of the foregoing,

- 1) Plaintiff's motion for summary judgment on defendant's defense of and counterclaim for inequitable conduct (Docket No. 202) is **ALLOWED**;
- 2) Plaintiff's motion for summary judgment precluding defendant's equitable defenses (Docket No. 206) is **ALLOWED**;
- 3) Defendant's motions for summary judgment based on laches (Docket No. 210), non-infringement (Docket No. 216) and obviousness (Docket No. 222) are **DENIED**;
- 4) Defendant's motion for reconsideration (Docket No. 199) is **DENIED**; and
- 5) Defendant's motion to strike (Docket No. 261) is **DENIED** as moot.

A jury trial on the remaining issues will proceed as scheduled on Monday, June 18, 2012.

So ordered.

/s/ Nathaniel M. Gorton

Nathaniel M. Gorton

United States District Judge

Dated April 19, 2012